

Application No.: 10/072,543  
Filing Date: February 8, 2002

### REMARKS

Prior to the foregoing amendment, Claims 1-6 and 8-36 stand pending. Claim 7 was previously cancelled. Claims 1, 12, 13, and 24 have been amended as noted above. Applicants note that basis in the original disclosure for amendments to the claims can be found, for example, at paragraph [0118] of the specification as published under U.S. Pub. No. 2002/0183718, and is thus proper under 35 U.S.C. § 112, paragraph 1. No new matter has been added.

#### Rejections under 35 U.S.C. § 103(a)

##### *Claims 1-12*

The Examiner rejected Claims 1-12 under 35 U.S.C. § 103(a) as unpatentable over U.S. Patent No. 6,500,200 to Kushnir in view of U.S. Patent No. 5,733,319 to Neilson et al, and found that “the bladders disclosed by Kushnir are capable of being placed on a breast in order to provide compression to the breast” (Office Action, p. 4).

Applicants disagree with the Examiner’s characterization. Nevertheless, to facilitate prosecution, Claims 1 and 12 have been amended as noted above to recite a “plurality of inflatable bladders configured to provide circumferential compression of a breast for the expression of intraductal fluid” and submit that because neither Kushnir nor Neilson, even when combined, teach or suggest this feature, the Examiner has not made a *prima facie* case of obviousness.

As stated in the M.P.E.P. § 2142, in order to establish a *prima facie* case of obviousness, the references when combined must teach or suggest all of the claim limitations. The Examiner bears the initial burden of factually supporting any *prima facie* conclusion of obviousness. M.P.E.P. § 2142. Applicants respectfully disagree with the rejection, and submit that the Examiner has not made a prima facie case of obviousness because even when the references are combined, the combination does not teach the invention as claimed.

Applicants submit that both Kushnir and Neilson fail to teach or suggest a plurality of inflatable bladders configured to provide circumferential compression of a breast for the expression of intraductal fluid as claimed, and that this functional element must be given patentable weight by the Examiner because it connotes particular structural attributes of the bladders required to perform this feature that are not taught or suggested by the prior art.

M.P.E.P. § 2173.05(g). Claim terminology that limits the structure of the claimed invention must be treated as a claim limitation. See M.P.E.P. § 2111.02; Corning Glass Works v. Sumitomo Elec., 868 F.2d 1251, 1257, 9 U.S.P.Q. 2d. 1962, (Fed. Cir. 1989). There is nothing inherently wrong with defining some part of an invention in functional terms, that is, by what it does rather than by what it is. M.P.E.P. § 2173.05(g); In re Venezia, 189 U.S.P.Q. 149 (C.C.P.A. 1976). Functional language must be evaluated and considered, just like any other limitation of the claim, for what it fairly conveys to a person of ordinary skill in the pertinent art in the context in which it is used. Id.

As noted in Applicants' previous response, Applicants submit that Kushnir's device, which includes four thin sheets 305, 306, 307, 308 (Fig. 3A) closely spot-welded together (col. 2, ll. 35-40) and divided into sections, is not configured for compression of a breast as claimed. Neilson fails to make up for this deficiency. Even assuming arguendo that the sections of Kushnir can be modified for breast compression, Applicants submit that any breast compression provided by Kushnir's device (e.g., the embodiment of Fig. 4), would be along an anterior-posterior axis which would not facilitate expression of intraductal fluid from the breast, and would be contrary to the recitation of Claims 1 and 12.

Furthermore, Applicants submit that neither of the cited references teach or suggest the following feature of Claims 1 and 12: "wherein each bladder has an inflated width of no more than about 3 inches and an inflated length of no more than about 4 inches." The Examiner found in the Office Action that Kushnir discloses the dimensions of each bladder as claimed (Office Action, page 2). Applicants disagree. Even assuming arguendo that they could be construed as inflatable bladders, the distance between two adjacent welded points in the garment 40 (Fig. 2A) cited by the Examiner has no correlation to, and thus is not relevant to the size dimensions of Kushnir's heat exchange sections. Therefore, Kushnir fails to teach or suggest that "each bladder has an inflated width of no more than about 3 inches and an inflated length of no more than about 4 inches." Neilson fails to make up for this deficiency. It does not appear that the Examiner has addressed Applicant's previously submitted argument in the present Office Action.

As previously noted, Applicants also submit that one of ordinary skill in the art would have no reason to modify a combination of Kushnir and Neilson such that "each bladder has an inflated width of no more than about 3 inches and an inflated length of no more than about 4

inches” as claimed. Kushnir merely teaches a garment with a variety of dedicated sections a (neck and head), b (portions of the individual’s arms), c (side portions of the individual’s torso), d (hip and thigh), and e (for the shin) defined by the general shape of the garment as well as emarginations 50, 52, 54, 56, and 58 part of which are in the form of lateral indentations or in the form of slits (col. 4, ll. 43-52, Figure 1). The dedicated sections of Kushnir are designed to envelope a surface area of the patient’s body sufficient for controlling body temperature. In other words, the sections of Kushnir (best depicted in Fig. 1 of Kushnir) must be large in order to accomplish Kushnir’s objective of promoting effective thermoregulation of the body. This objective is profoundly different from Applicant’s objective of providing circumferential compression of a breast to obtain a nipple aspirate, which requires much smaller claimed inflatable bladder dimensions to achieve this purpose. Modifying Kushnir’s sections to the claimed dimensions would be grossly insufficient to provide effective thermoregulation of a patient and would thus render Kushnir’s device unsuitable for its purpose, and act as a major disincentive to the combination proposed by the Examiner. *See Tec Air Inc. v. Denso Mfg. Michigan Inc.*, 192 F.3d 1353, 1360 (Fed. Cir. 1999)(if a proposed modification would render the prior art device being modified unsuitable for its intended purpose, the proposed modification would not have been obvious). Moreover, Applicants contend that Kushnir’s emphasis on providing sections large enough to provide an effective cover of the human body by the garment sufficient to properly control body temperature teaches away from creating inflatable bladders with the claimed dimensions, and further necessitates a finding of non-obviousness.

For the foregoing reasons, Applicants submit that Claims 1 and 12 are allowable over the cited references, and request that the obviousness rejections be withdrawn. Applicants note that Claims 2-11 depend from Claim 1 or other claims that depend therefrom and contain all of the limitations thereof in addition to further distinguishing features; thus Applicants submit that these claims are in condition for allowance as well.

#### *Claims 13-36*

Claims 13-36 were also rejected as unpatentable over Kushnir in view of Neilson. Applicants respectfully point out that the Examiner has not discussed in the Office Action how

the combination of Kushnir and Neilson teach or suggest all of the limitations of specific Claims 13-36. Applicants submit that the combination of cited references fails to teach or suggest every element of these claims, and thus a *prima facie* case of obviousness has not been made. Applicants submit that neither Kushnir nor Neilson teaches or suggests, *inter alia*, features of the bladders, as in amended Claims 13 and 24, “configured to provide a circumferential compressive force anatomically adjacent to the lactiferous sinus of a breast for the purpose of expressing intraductal fluid.” As noted above, Applicants submit that this functional element must be given patentable weight by the Examiner because it connotes particular structural attributes of the bladders required to perform this feature. M.P.E.P. § 2173.05(g). Applicants submit that Kushnir’s device, which includes four thin sheets 305, 306, 307, 308 (Fig. 3A) closely spot-welded together (col. 2, ll. 35-40) and divided into sections, is not configured for circumferential compression of a breast as claimed. Kushnir’s heat-exchanging device is designed for a different application than Applicant’s device: to control a patient’s body temperature, enveloping a substantial surface area of the patient’s body. Thus, Applicants submit that one of ordinary skill in the art would have no reason to modify Kushnir’s device as claimed. Even assuming *arguendo* that the sections of Kushnir can be modified for breast compression, Applicants submit that any compression provided (e.g., the embodiment of Fig. 4), would not be circumferential, but rather along an anterior-posterior axis which would not facilitate expression of intraductal fluid from the lactiferous sinus, and would be contrary to the recitation that the circumferential compressive force . . . anatomically adjacent to the lactiferous sinus for the purpose of expressing intraductal fluid” as claimed. Neilson, which merely discloses a balloon 34 that serves to retain shaft 32 in a fixed position within the urethra (col. 4, ll. 55-65), does not make up for this deficiency. Thus, Applicants submit that Claim 13 and 24 are allowable over the cited reference. Claims 14-23 depend from Claim 13 or other claims that depend therefrom and recite all of the features thereof in addition to further distinguishing features; thus Applicants submit that these claims are also allowable.

Furthermore, in regards to Claims 25-36, neither Kushnir nor Neilson teaches or suggests, *inter alia*, bladders “configured to provide radially symmetrical compression of a breast along a longitudinal axis for the purpose of expressing intraductal fluid.” This functional element must be given patentable weight by the Examiner because it connotes particular attributes of the

bladders required to perform this feature. M.P.E.P. § 2173.05(g). As noted in the discussion of Claims 13-24 above, Kushnir's heat-exchanging device is designed for a different application than Applicant's device: to control a patient's body temperature, enveloping a substantial surface area of the patient's body. Thus, Applicants submit that one of ordinary skill in the art would not be motivated to modify Kushnir's device as claimed. Even assuming arguendo that the sections of the device of Kushnir can be modified for breast compression, Applicants submit that any compression provided by Kushnir's device (e.g., the embodiment of Fig. 4) would be along an anterior-posterior axis which would not facilitate expression of intraductal fluid, and would be contrary to the recitation that the bladders are "configured to provide radially symmetrical compression of a breast along a longitudinal axis for the purpose of expressing intraductal fluid." Neilson fails to make up for this deficiency. Thus, Applicants submit that Claim 25 and 36 are allowable over the cited reference. Claims 26-35 depend from Claim 25 or other claims that depend therefrom and recite all of the features thereof in addition to further distinguishing features; thus Applicants submit that these claims are also allowable.

No Disclaimers or Disavowals

Although the present communication may include alterations to the application or claims, or characterizations of claim scope or referenced art, the Applicants are not conceding in this application that previously pending claims are not patentable over the cited references. Rather, any alterations or characterizations are being made to facilitate expeditious prosecution of this application. The Applicants reserve the right to pursue at a later date any previously pending or other broader or narrower claims that capture any subject matter supported by the present disclosure, including subject matter found to be specifically disclaimed herein or by any prior prosecution. Accordingly, reviewers of this or any parent, child or related prosecution history shall not reasonably infer that the Applicants have made any disclaimers or disavowals of any subject matter supported by the present application.

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Co-Pending Applications of Assignee

Applicant wishes to draw the Examiner's attention to the following co-pending applications of the present application's assignee.

Serial Number	Title	Filed
10/209,210	DISPOSABLE PATIENT INTERFACE FOR INTRADUCTAL FLUID ASPIRATION SYSTEM	7/30/02
11/099,295	METHOD AND APPARATUS FOR NONINVASIVE INTRADUCTAL FLUID DIAGNOSTIC SCREEN	4/5/05
11/775,751	METHOD AND APPARATUS FOR NONINVASIVE INTRADUCTAL FLUID DIAGNOSTIC SCREEN	7/10/07
11/775,768	DISPOSABLE PATIENT INTERFACE FOR INTRADUCTAL FLUID ASPIRATION SYSTEM	7/10/07

**CONCLUSION**

For the reasons presented above, Applicants submit that the present application is in condition for allowance and respectfully request same. If any issues remain, the Examiner is cordially invited to contact Applicants' representative at the number provided below in order to resolve such issues promptly.

Please charge any additional fees, including any fees for additional extension of time, or credit overpayment to Deposit Account No. 11-1410.

Respectfully submitted,

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Dated: 1/21/08

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